DETAILED ACTION

1. Applicant's amendment, remarks, and IDS filed 5/16/11 have been entered.

2. Claims 1-4, 7, 9, 19, 20, 31, 32, and 50-52 are under examination.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-4, 7, 9, 19, 20, 31, 32, and 50-52 stand rejected under 35 U.S.C. 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a written description rejection for the introduction of new matter into the claims.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically, an antibody (now humanized) defined by the CDRs of SEQ ID NO:10 (light chain) and SEQ ID NO:18 (heavy chain).

Applicant now cites Figures 4a-c of the pre-grant publication.

The Figures disclose only the 1G4 V_L (SEQ ID NO:10) and V_H (SEQ ID NO:18) regions. They do not support full antibodies, comprising both a V and C region, defined only by the 3 CDRs (each) of the V_L and V_H regions.

Applicant now cites paragraphs [0020], [0037], and [0038] of the pre-grant publication.

Paragraphs [0020], [0037] disclose nothing about the specific antibodies of the claims. Paragraph [0038] discloses only the CDR3s of the V_L and V_H (SEQ ID NOs:45 and 49,

respectively) of the antibody 1G4 V_L (SEQ ID NO:10) and V_H (SEQ ID NO:18) regions. There is no disclosure of an antibody further defined by the CDRs 1 and 2 of the antibody 1G4 V_L and V_H regions.

Applicant argues, "…one of skill in the art would understand that the polypeptides of SEQ ID NOs: 10 and 18 depicted in Figures 4a and 4b, respectively, *necessarily* contain all the CDRs of the *1G4* antibody".

Applicant's statement is certainly true, but it does not show demonstrate that Applicant was in possession of, or even envisioned, a genus of antibodies defined only by the 6 CDRs of the 1G4 antibody.

Applicant argues that the skilled artisan could readily identify the CDRs of the antibody defined by SEQ ID NOs:10 and 18 and that methods for generating antibodies were known in the art.

Applicant's argument is true as far as it goes; but it does not demonstrate that Applicant was in possession of, or even envisioned, a genus of antibodies defined only by the 6 CDRs of the 1G4 antibody.

Applicant cites Kabat et al. (1991) and argues that the skilled artisan could have figured out the CDR1s and CDR2s of the antibody defined by SEQ ID NO:10 (light chain) and SEQ ID NO:18 (heavy chain).

Applicant essentially admits that the specification does **not** disclose the CDR1s and CDR2s of the antibody defined by SEQ ID NO:10 (light chain) and SEQ ID NO:18 (heavy chain). It is then unclear how Applicant can convincingly argue that Applicant was in possession of, or even envisioned, a genus of antibodies defined by only the 6 CDRs of the 1G4 antibody. Accordingly, the specification does not adequately describe an antibody defined only by the 6 CDRs of the V_L and V_H chains of SEQ ID NOs:10 and 18, respectively.

5. No claim is allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on (571) 272-0878.

8. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/G.R. Ewoldt/
G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600